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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/795,830

03/08/2004

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ZIM0417

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7590 12/11/2008
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EXAMINER

GEORGE, TARA R

ART UNIT

PAPER NUMBER

3733

MAIL DATE

DELIVERY MODE

12/11/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

DETAILED ACTION

Priority

Applicant submitted a petition to accept an unintentionally delayed claim under 25 U.S.C. § 120 on 04/02/2007. This petition has been granted. Therefore, the prior art reference (US 2004/0122305) to Grimm et al. does not constitute prior art. The previous rejection under 35 U.S.C. § 102(e) has been withdrawn and a new ground of rejection has been established below.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 2 recites the phrase “and/or” which renders the claim as unclear.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims are rejected under 35 U.S.C. 102(b) as being anticipated by Barnett et al. (5904691).

With respect to claim 15, Barnett discloses a surgical system for use during an orthopedic surgical procedure at a surgical site of a patient's body, the system comprising: a surgical navigation system including means (eg. computer) for tracking the position of an object during a surgical procedure; a navigated orthopaedic guide (2) including means (eg. biopsy guide) for being tracked by the surgical navigation system to guide positioning of the orthopaedic guide (200 + 100 + 106) at a desired position relative to the surgical site, the orthopaedic guide including means (4a-4d) for establishing a datum at a desired position relative to the surgical site; and a surgical component including means for engaging the datum positioned by the orthopaedic guide to locate the surgical component at a desired position relative to the surgical site (102a-102d) (note col. 5 line 41 – col. 6 line 22).

As for claim 2, Barnett further discloses the surgical system of claim 15 wherein the means for establishing a datum comprises means for establishing one or more datums relative to the surgical site selected from the list consisting of pins, screws, bars, fins, rails, dovetails, planar surfaces, holes, slots, and/or notches (see fig. 1).

As for claim 3, Barnett further discloses the surgical system of claim 15 wherein the means for establishing a datum comprises means for establishing an intermediate datum separate from the guide itself (note use of 102a-102d).

As for claim 4, Barnett further discloses the surgical system of claim 15 wherein the means for establishing a datum comprises a guide body including a plurality of holes

through the body for guiding the placement of pins relative to the surgical site (see fig. 1).

As for claim 8, Barnett further discloses the surgical system of claim 15 wherein the means for establishing a datum includes a base member (100) and a datum guide member (200) connected to the base member such that the position of the datum guide member is adjustable relative to the base member to a desired datum guide member position as indicated by the surgical navigation system.

As for claim 16, Barnett further discloses the system of claim 15 wherein the means for tracking comprises multiple sensors (4a-4d) to detect and triangulate the position of the orthopaedic guide.

As for claim 18, Barnett further discloses the system of claim 15 wherein the means for establishing a datum comprises a drill guide to guide a drill in forming a hole in a bone at the surgical site (see col. 5 lines 37-40).

As for claim 19, Barnett further discloses the system of claim 15 wherein the means for establishing a datum comprises at least one hole (106) in the orthopaedic guide to guide placement of a pin adjacent the surgical site.

As for claim 21, Barnett further discloses the system of claim 15 wherein the surgical component comprises a cut guide to guide a cutter to cut a bone to receive an implant (see col. 5 lines 37-40).

As for claim 25, Barnett further teaches the system of claim 15 wherein the means for engaging the datum comprises at least one hole (106) formed in the surgical component to receive the datum in the form of a pin.

With regard to statements of intended use and other functional statements, they do not impose any structural limitations on the claims distinguishable over Barnett which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Furthermore, the law of anticipation does not require that the reference “teach” what the subject patent teaches, but rather it is only necessary that the claims under attack “read on” something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 9, 10 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barnett, as applied to claim 15, in view of Bowman et al. (4952213).

As for claims 9, 10 and 23, Barnett does not disclose wherein the base member is able to be secured to a distal portion of a femur and the datum guide member is adjustable relative to the base member to establish a datum having desired flexion-extension and varus-valgus angles as indicated by the surgical navigation system;

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wherein the base member is able to be secured to a proximal portion of a tibia and the datum guide member is adjustable relative to the base member to establish a datum having desired posterior slope and varus-valgus angles as indicated by the surgical navigation system; and wherein the cut guide comprises a distal femoral cut guide.

Bowman teaches wherein a base member (24) is able to be secured to a distal portion of a femur and a guide member (10) is adjustable relative to the base member to establish desired flexion-extension and varus-valgus angles (see fig. 1); wherein the base member is able to be secured to a proximal portion of a tibia (see fig. 1) and the guide member is adjustable relative to the base member to establish a desired posterior slope and varus-valgus angles (see fig. 1); and wherein the cut guide comprises a distal femoral cut guide (see fig. 1) in order to provide an apparatus for accurately positioning a cutting tool. It is noted that the features taught by Bowman are very well known in the art. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the base member and guide member of Barnett in view of Barnett in order to provide the guide the ability to more accurately position a cutting tool.

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Barnett, as applied to claim 15, in view of Hunter et al. (6235038).

As for claim 17, Barnett does not disclose wherein the means for being tracked comprises an electromagnetic coil attached to the orthopaedic guide, the electromagnetic coil producing a signal detectable by the means for tracking. Hunter teaches an electromagnetic coil attached to the orthopaedic guide, in order to produce a

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signal that can be tracked (see abstract and col. 4 lines 40-47). It would have been obvious to one of ordinary skill in the art at the time of the invention that anything used to generate a signal is an equivalent means to the means for being tracked of Barnett.

Allowable Subject Matter

Claims 11-14 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

The affidavit filed on 4/4/2008 under 37 CFR 1.131 is sufficient to overcome the Couture reference.

Applicant's arguments with respect to claims 2-4, 8-10, 15-19, 21 and 23 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's presentation of new evidence (note this is reference to the affidavit) necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TARA R. GEORGE whose telephone number is (571)272-3402. The examiner can normally be reached on M-F from 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/T. R. G./

Examiner, Art Unit 3733

/Eduardo C. Robert/

Supervisory Patent Examiner, Art Unit 3733